

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-527

C# M#

HERSHFIELD et al.

TC/A.U.

1652

Serial No. 09/762,097

Examiner: Patterson

Filed: August 23, 2001

Date: March 24, 2004

Title: URATE OXIDASE



Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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MAR 29 2004

OFFICE OF PETITIONS

Sir:

**RESPONSE/AMENDMENT/LETTER**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment 0 minus highest number  
previously paid for 20 (at least 20) = 0 x \$ 18.00 \$ 0.00

Independent claims after amendment 0 minus highest number  
previously paid for 3 (at least 3) = 0 x \$ 86.00 \$ 0.00

If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) \$ 0.00

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) \$ 420.00

Terminal disclaimer enclosed, add \$ 110.00 \$ 0.00

☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) \$ 0.00

☐ Please enter the previously unentered, filed

☐ Submission attached

**Subtotal \$ 420.00**

If "small entity," then enter half (1/2) of subtotal and subtract -\$ 0.00

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee (\$180.00) \$ 0.00

Assignment Recording Fee (\$40.00) \$ 0.00

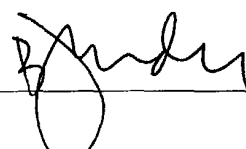
Other: 0.00

**TOTAL FEE ENCLOSED \$ 420.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

1100 North Glebe Road, 8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100  
BJS:pp

NIXON & VANDERHYTE P.C.  
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: 

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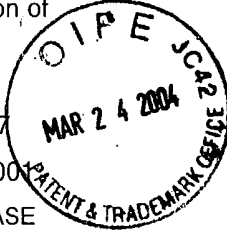
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**TOTAL FEE ENCLOSED \$ 420.00**

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Signature: \_\_\_\_\_



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HERSHFIELD et al.

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\* \* \* \* \*

March 24, 2004

Commissioner for Patents  
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Sir:

**RESPONSE**

Responsive to the Office Action dated October 24, 2004, entry and consideration of the following remarks and attached references are requested.

A copy of the REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 filed November 7, 2003 and STATUS REQUEST filed separately herewith are attached. Consideration of the REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 and a Decision on the same are requested prior to the Examiner's issuance of a further Action as the Patent Office Decision on the attached REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 may affect the scope of the examination in any subsequent Office Action.

As noted in the attached REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181, reconsideration and withdrawal of the

alleged lack of unity of invention, or restriction requirement, is requested along with examination of all the claimed subject matter in a new non-final Office Action.

Specifically, the Decision mailed September 10, 2003, indicates that a Request for Reconsideration of the Decision must be "made by way of a renewed petition". See, page 3 of the Decision. The attached REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 was filed November 7, 2003.

The Applicants filed a Rule 181 Petition on April 15, 2003, which requested that the Commissioner invoke his supervisory authority and have the restriction requirement of November 27, 2001, withdrawn. The remarks of the Rule 181 Petition filed April 15, 2003, are of record and the Applicants believe that the contents of the same should not need to be repeated herein. To the extent required, the comments of the Rule 181 Petition filed April 15, 2003, are incorporated herein by reference and the attachments thereto are similarly incorporated.

The Decision dated September 10, 2003, granted-in-part the Rule 181 Petition filed April 15, 2003, in that the restriction requirement of November 27, 2001, has been "removed". The Decision indicates that

"The polypeptides will be examined together with the method of use. However, claims directed to polynucleotides are not rejoined to the polypeptides because these inventions are not linked by a special technical feature which makes a contribution over the prior art." See, page 3 of the Decision.

Specifically, the Decision indicated that a restriction requirement between claims 2-5 and 6-17 "drawn to recombinant chimeric uricase proteins and methods of increasing non-deleterious PEG attachment site on uricase proteins" and claims 6-15 "drawn to polynucleotides, vectors and host cells encoding the recombinant chimeric

uricase proteins" was appropriate because the subject matter of these groups of claims "lack the same or corresponding special technical feature". See, page 2 of the Decision. The following reason was given as a basis for the finding that the subject matter of these groups of claims lack the same or corresponding technical feature:

Miura et al., (of record [European Journal of Biochemistry, 223, 141-146 (1994)]) teaches a recombinant chimeric uricase protein which has been modified to insert one or more lysine residues wherein said protein has two or more mammalian amino acid sequences (see abstract in particular), thereby teaching Applicant's invention as presently recited in claim 2. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention." See, page 2 of the Decision.

The Examiner has determined however in an Office Action mailed October 24, 2003, that the claims, including claim 2, are patentable over "Mura et al." (see, page 3 of the Office Action dated October 24, 2003 (Paper No. 21)), which the Applicants believe is a reference to the Miura et al. reference cited as the basis in the Decision for the holding of an alleged lack of unity of invention.

As the Examiner has now affirmed that the claims of Group I recited on page 2 of the Decision are patentable over the art, the basis for the restriction requirement asserted in the Decision no longer supports maintaining the restriction requirement. Accordingly, the Commissioner is requested in the attached REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 to instruct the Examiner to consider all of the claimed subject matter and issue a new action in place of the Office Action mailed October 24, 2003. The Examiner is similarly requested herein to consider all of

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the claimed subject matter and issue a new action in place of the Office Action mailed October 24, 2003.

Reconsideration of the Decision is requested along with a new Office Action on the merits of all the claimed subject matter.

As the Patent Office PAIR page does not indicate receipt and entry of the REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181 filed November 7, 2003, a further copy of the same is attached and being separately filed herewith with the attached STATUS REQUEST.

Consideration of the following is requested in response to the Office Action of October 23, 2003.

Claims 2-17 are pending.

Attached is a copy of the following references:

Wu et al., J. Mol Evol (1992) 34:78-84;

Hershfield et al., PNAS 88, pp 7185-7189 (August) 1991;

Henny et al, The New England Journal of Medicine, vol 278, No. 21, pp 1144-1146 (May 23, 1968); and

Conley et al., Biochem J., 187 (1990) pp. 727-732.

The attached Wu et al reference is attached in response to the Examiner's comment on page 4 of the Office Action dated October 23, 2003. Consideration of the attached Wu et al reference and an indication of the same on the record are requested.

The attached Hershield et al. reference is being again submitted as evidence that the volume of the article is "88" as opposed to "68" listed in the Examiner's PTO-892. Correction of the record in this regard is requested.

The attached Henney and Conley references are again being submitted as the Examiner has lined-through these references in the initialed PTO 1449 Form received with the Office Action dated October 23, 2003. Given the Examiner's comments on pages 3-4 of the Office Action dated October 23, 2003 with regard to the Examiner's previous lining-through of cited art, the undersigned is resubmitting a further copy of these references. Consideration of the attached references and an indication of the same with the Examiner's next Communication are requested.

The allowance of claim 5, and the indication that claims 3 and 4 contain allowable subject matter, are acknowledged, with appreciation. See, page 4 of the Office Action dated October 23, 2003.

The Examiner's efforts to locate copies of the previously-filed art is acknowledged, with appreciation. See, page 4 of the Office Action dated October 23, 2003.

The Section 112, first paragraph, rejection of claims 2 and 16-17, is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner's acknowledgement that the specification is "enabling for SEQ ID NO: 2, 4 and 8-11" is acknowledged, with appreciation. See, page 2 of the Office Action dated October 23, 2003. The Examiner acknowledges

therefore that the applicants have at least taught how to make and use 6 different species within the claimed genus. Moreover, the Examiner has implicitly indicated that the subgenuses of claims 3 and 4 are supported by an enabling disclosure.

The applicants respectfully submit that one of ordinary skill who is able to make and use the species of claim 5 and species of the subgenuses of claims 3 and 4 would be able to make and use the subject matter of claims 2, 16 and 17.

The Examiner again makes a reference to page 11, lines 12 to 19 of the specification in support of the Section 112 rejection. See, page 3 of the Office Action dated October 23, 2003. The Examiner is again urged however to consider the paragraph following the cited section of the specification (i.e., page 11, line 20 through page 12, line 3) wherein the applicants explain that it was subsequently appreciated that amino acid residue 291 of the baboon uricase is lysine but the corresponding residue in pig is arginine and that the ApaI restriction site present in both cDNAs was exploited to construct a chimeric uricase in which the first 225 amino acids are derived from the pig cDNA and the carboxy terminal 79 are derived from the baboon cDNA. This passage of the specification goes on to describe the construction of the presently claimed invention and the fact that the claimed uricases are fully as active as compared to the unmutated native pig uricase in approximately more than fourfold active than unmutated native baboon uricase. The applicants submit that one of



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ordinary skill in the art could use the approach of the present application to make and use the claimed subject matter.

Reconsideration and withdrawal of the Section 112, first paragraph, rejection of claims 2, 16 and 17, are requested.

A new non-final Office Action on the merits of all the claimed subject matter or a Notice of Allowance with respect to all of the claimed subject matter is requested, with return of an indication of consideration of the attached art, and a favorable Decision on the attached REQUEST FOR RECONSIDERATION AND RENEWED PETITION UNDER RULE 181.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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